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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,390	01/22/2004	Koral Embil	EDKO-001	2411

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1611	
MAIL DATE	DELIVERY MODE
07/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/761,390	EMBIL ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16-26 and 31-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16-26 and 31-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-2-09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of RCE, amendment, IDS and response all dated 4-2-09 is acknowledged.

Claims 1-14, 16-26 and 31-35 are pending.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4-2-09 has been entered.

2. The previous rejections of record are withdrawn and the following new rejections applied:

Claim Rejections - 35 USC § 112

3. Claims 1-14, 16-26 and 31-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. Instant claims have been amended to recite viscosity of less than about 25,000. Applicants state that the support comes from paragraph 0069 of the published application. However, a careful review of the same does not support the claimed limitation. Instead, the specification only supports that "in general the viscosities of the

formulations may be up to 200,000 cps, preferably up to 100,000 cps, more preferably in the range 5,000 to 50,000 cps, yet more preferably 5,000 to 15,000 cps, e.g. about l0,000 cps. The use of formulations having lower viscosities, e.g. of the order of about l0,000 cps, is particularly preferred when dispensing these/from systems having side-by-side chambers or compartments from which the product is dispensed by the application of external pressure means. In particular, it has been found when using such systems that it is important to ensure that each formulation (e.g. cream, gel or lotion) should be free flowing to the extent that this essentially remains at the base of the container where the suction tube orifice is located. This orifice must be kept inside each formulation at all times otherwise air will enter the system causing inaccurate amounts of cream to be dispensed. On the other hand, it is important that the Viscosity of each formulation should not be too low since the liquid will not stick to the skin. The use of low viscosity formulations has the added advantage that non-pressurized systems may be used to dispense these:.

The claim as recited fails to define the lower limit of the viscosity and accordingly, instant specification does not state explicitly state that the viscosity of less than about 25,000, where the minima is undefined. Further, applicants have not provided the description of a composition with the claimed viscosity and the claimed emulsions comprising first and second phases. Applicants state that the support for the first and second phases comes from paragraph 0069 of the published application. However, a careful review of the same does not support the claimed limitation, let alone any emulsions with the claimed viscosities.

5. Claims 1-14, 16-26 and 31-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Instant claims recites “less than about 25,000”, which is indefinite because while less than 25000 sets a maximum of

25000 and any viscosity below this maxima, the phrase "about" allows for approximation and does not define what is the maximum viscosity limit allowed or required.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-14, 16-26 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/912726 (WO) in view of US 7060732 to Vishnupad et al ('732) and US 5955109 to Won et al (109) or WO in view of '732, '109 and EP 306236 (hereafter EP).

8. WO teaches a package comprising components which, upon being mixed, are capable of forming a pharmaceutical composition that is effective in treating acne, the composition tending to degrade prematurely, one of the components comprising an oxidizing agent and another of the components comprising an antibiotic which is effective against acne-associated bacterial species, the components separated one from the other in the package, one component having a viscosity within about 50 % of the viscosity of the other component. WO teaches that the package components which, upon being mixed, are capable of forming a pharmaceutical composition that is effective in treating ache, one of the components comprising a benzoyl peroxide gel and another of the components comprising a gel of erythromycin and hydroxypropylcellulose; and containers for holding the components in the package separated one from the other; the components having viscosities such that, upon the application of a uniform forces to the components, substantially equal volumes of the components are capable of being

dispensed simultaneously from the containers (abstract, page 7, L 1-10-12 and l 23-27). WO teaches combination of clindamycin or erythromycin with benzoyl peroxide. For the gelling agent, WO teaches a hydroxylated vinylic polymer but not state if the polymer is capable of entrapping as in the instant claim 1.For the descript of the packaging means, see pages 8-9 of WO reference and meets instant claims 5 and 6. WO states that the composition is stable on storage (page 11).For the claimed viscosities and the forms of the components, WO states that the viscosities may be same or different and when combined the components should yield the desired viscosity and that the components may range from solids to liquids such as gels, creams, lotions etc (page 23, L 1-12, l 21-page 24, L 7), allowing the user to dispense amounts that are substantially equal. WO teaches viscosities in the range of 200000 (page 25) and not the claimed less than 25000 cps. In addition to the antibiotic clindamycin, WO teaches several actives such as tretinoin, antifungal compounds etc (page 27).

9. For the claimed phases, WO does not teach emulsions, but teaches that the active agents are dissolved in water or other solvents depending on their solubility (page 28) and further teaches addition of surfactants for even distribution of compounds such as benzoyl peroxide (page 30).

10. WO does not teach the claimed entrapping polymers.

11. Applicants admit in the instant specification that 109 teaches the claimed entrapping porous polymers (microsponge)that comprises the same monomeric units as that of instant claim 3 (see abstract). The composition of '109 is effective for treating acne. It is stated that retinoic acid is trapped inside and diffused in controlled manner

from the microsponge (col. 2), based on the pore volume (col. 3, L 14-24). The porous polymeric beads or microspheres of '109 have the same pore diameter, particle size shape as claimed in the instant claim 3 (col. 4, L 150) and are made of the same components as instant (col. 6-7). In addition to retinoic acid, '109 also teach compositions containing porous polymers that entrap benzoyl peroxide (see example in col. 8) as an active ingredient.

EP also teaches controlled release of several skin care and hair care active agents such as benzoyl peroxide, salicylic acid, minoxidil etc., from a composition containing a microsponge polymeric system (the same microsponge as that claimed in the instant invention). In particular, EP (as well as Wester) teaches the treatment of acne with benzoyl peroxide. For the various active agents of EP, see pages 2-5, 7, page 12, L 40-45 and examples and on page EP teaches a number of combinations of the active agents.

12. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ the microsponge polymeric delivery material of '109 in the composition of WO, either in one or both compartments, because EP as well as 109 suggests that the porous polymeric material forms a continuous network open to the exterior particles, permitting outward diffusion of the impregnated active agents in a controlled fashion.

Neither WO nor '109 teach the emulsions formulation of first and second ingredients. However, both are directed to acne treating compositions.

'732 also teach acne treating compositions comprising separately packaged active ingredients with a common dispenser (abstract and col. 2, L 40-57). In particular, '732 teach benzoyl peroxide and antibiotic or antibiotic and retinoid combinations (col. 2, l 58-64. While '732 states the compositions are substantially anhydrous, they state that if the composition is not water sensitive it is still allowed so as to prepare emulsions(col. 3, L 60-65 & col. 6). '732 state that the composition may have a viscosity in the range of 10000 to 1000000 cps (col. 6, L 19-24 and l 45-47). '732 further teaches preparation of benzoyl peroxide compositions where the compositions contain surfactant and according to '732 the first and second compositions may be in the form of a gel, emulsion, lotion etc (col. 3, L 25-35).

All of the references cited teach two compartment dispenser containing first and second actives for acne treatment, in particular, the same actives i.e., benzoyl peroxide, antibiotic, retinoic acid etc. All of the references also desire viscosities of the compositions such that the compositions may be easily pumped. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare an appropriate emulsion formulation of the first and second compositions of WO depending on the solubilities of the active agent (suggested by WO or '732) and further optimize the viscosities of the two compositions in the package so as to be able to dispense the desired amounts of the two components either equal or varying amounts because '732 suggests viscosities greater than 5000, ranging from 10000 to 100000 for presenting good feel to the user and also that the viscosities differ by no greater than25% between the first and second compositions and WO suggests

that the viscosities may vary as long it enables the user to dispense the desired (same or varying) amounts from two compartments. Applicants have not provided any unexpected advantage of the claimed viscosity and further '732 suggests lower viscosity ranges. With respect to lipophilicity, applicants failed to establish any unexpected advantage of the substantially same lipophilicity whereas the references suggests the same compositions i.e., emulsions in both compartments. Hence, choosing the same or different emulsions would have been within the scope of a skilled artisan.

Response to Arguments

13. Applicant's arguments filed 4-2-09 have been fully considered but they are not persuasive.

14. The arguments pertaining the previous rejections are moot because new references have been cited. Further, Applicants argue that without substantially same lipophilicity, there is dose dumping or ineffectual delivery. However, newly cited '109 reference teaches controlled release from the entrapping polymers that is effective in acne treatment. The references now cited teach a wide range of viscosities and the burden is on applicants to show that the claimed range provides unexpected advantage, even though it is suggested within the range of the newly cited art. The new rejections provide the motivation to optimize viscosities and also include emulsions as opposed to aqueous compositions, as argued. The argument regarding caboxy vinyl polymer of WO 26 is moot because instant rejection provides motivation to employ the claimed polymer.

15. With reference to the previous declarations of Katz and Lochhead and the present declaration of Nacht, the declarations have been considered but not persuasive

because the declaration of Nacht pertains to explaining the teachings of WO 26 and is no longer applied in the rejection. Instant new rejection provides emulsion forms of active agents and not necessarily aqueous forms alone. The references also suggest adjusting viscosities so as to be able to pump in desired amounts. With respect to the argument that dose dumping of clindamycin occurs with polymer of EP, examiner notes that the same polymer and drug are also employed in the instant invention. Therefore, the declaration, which is only an opinion without the actual comparison between the polymers of instant and prior art are not persuasive. The declarations of Katz and Lochhead have been addressed in the previous action and incorporated herewith.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
July 6, 2009